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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,630	01/18/2001	James H. Goethel	L-F / 180DV	8472
26875	7590	01/13/2005	EXAMINER	
WOOD, HERRON & EVANS, LLP			HAYES, MICHAEL J	
2700 CAREW TOWER			ART UNIT	PAPER NUMBER
441 VINE STREET			3763	
CINCINNATI, OH 45202			DATE MAILED: 01/13/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/764,630	GOETHEL ET AL.
	Examiner	Art Unit
	Michael J. Hayes	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 04 November 2004.  
 2a) This action is FINAL.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,3-6 and 8-13 is/are pending in the application.  
 4a) Of the above claim(s) 13 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1,3-6 and 8-12 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 07 February 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1)  Notice of References Cited (PTO-892)  
 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_  
 5)  Notice of Informal Patent Application (PTO-152)  
 6)  Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

Newly submitted claim 13 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 13 recites a rearward extension with a knurled interior cavity, whereas the claims originally examined on the merits recite an extension that is enveloped by a coupling mechanism.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 13 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6, 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the injector in claim 5 which has mating sections to align with the syringe mating sections. The injector is only functionally claimed, but established as an element that is mated to the syringe in claim 5. The injector needs to be positively claimed

because it is an essential element in the arrangement of the syringe and injector mating sections.

In claim 8 the coupling mechanism on the plunger drive ram is only functionally claimed.

Applicant recites an extension having no discontinuity “within an area enveloped by a coupling mechanism,” but does not positively recite the coupling mechanism. The coupling mechanism is an essential element to have the drive ram engage and move the plunger within the syringe.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-6, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Nightingale (US Patent No. 3747479). Nightingale discloses a syringe capable of mounting to an injector, including a barrel, plunger with a rearwardly facing drive ram engaging coupling element 72 that is knurled, a discharge tip, a conical front wall, syringe mating sections including annular flange, and an interior cavity within the coupling element 72. While a handle extends out of the barrel, the coupling element 72 does not extend out of the barrel in at least one position of the plunger. The area adapted to be within an area enveloped by a coupling mechanism (i.e., the knurled area) exhibits no discontinuity in area. See fig. 7.

Claims 1, 3-6, 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by REILLY (US Patent No. 4,677,980). Reilly discloses an injector, including a barrel, plunger with a rearwardly facing drive ram engaging coupling element 156 that is knurled, a discharge tip, a

conical front wall, syringe mating sections including annular flange, a moveable faceplate 14' being rotatable to lock the syringe in an arrangement with the injector, and mating sections 132 to align with the injector. See figs. 2 and 17.

Claims 1, 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by DENSMORE (US Patent No. 5,007,904). Densmore discloses an injector, including a barrel, plunger with a rearwardly facing drive ram engaging coupling element that is knurled (i.e., has ridges on a rearwardly facing projection from the plunger), a discharge tip, a conical front wall, syringe mating sections including annular flange, and a cavity. See figs. 2, 4, and 6.

Claims 1, 3-6, 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by NEER et al. (US Patent No. 5,300,031). Neer shows a syringe having a barrel, plunger, coupling element 96, conical front, syringe mating sections comprising an annular flange fixed to the syringe body (See Figs. 4,5,11,12). A portion of the extension shows no substantial discontinuities in adjacent transverse cross-sections within an area of the enveloped area. See fig. 12. Neer also discloses a movable face plate 127 movable by a rotatable lever 138 to facilitate syringe mounting. See Figs. 6-9.

### ***Response to Arguments***

Applicant generally argues that Nightingale does not disclose a rearward extension that is capable of being within an area enveloped by a coupling mechanism. The examiner disagrees because the extension from the plunger does have this capability due to its elongated structure. Applicant has not positively recited the coupling mechanism in claims 1, 3-6, and 12.

With respect to claim 12 Nightingale Applicant argues that Nightingale discloses a discontinuity along its length. The examiner notes that though there is a discontinuity, this discontinuity is not within an area capable of being enveloped by a coupling mechanism.

In claims 1, 8, and 12 Applicant recites structure “within an area enveloped by a coupling mechanism.” This claim limitation is construed as requiring the specific structure in some portion of the area enveloped by a coupling mechanism. This is distinguished from a limitation reciting within the area enveloped by a coupling mechanism, which requires the specific structure within the total area enveloped.

Applicant argues that Reilly does not disclose a knurled extension. The examiner does not agree because Applicant has not established a specific definition in his specification as filed, and the common definition of knurl is “a protuberance, as a knob or knot,” or “one of a series of small ridges.” (Webster’s II New Riverside University Dictionary, 1994). The examiner’s maintains the position that Reilly discloses a knurled extension.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi, can be contacted at (703) 308-2698. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

Art Unit: 3763

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh  
10 January 2005



**MICHAEL J. HAYES  
PRIMARY EXAMINER**